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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/841,894	04/25/2001	Patricia A. Billing-Medel	6083.US.D2	6734

7590 02/16/2005

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EXAMINER	
FREDMAN, JEFFREY NORMAN	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 02/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/841,894	BILLING-MEDEL ET AL.	
	Examiner	Art Unit	
	Jeffrey Fredman	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2005* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-16, 33, 35,38 and 39* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-16,33,35,38 and 39* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Priority

1. Applicant's claim for priority to parent Application 08/850,713 is acknowledged. However, 08/850,713 does not provide descriptive support for the current claim since that Application lacks the sequence of SEQ ID Nos: 15 and 16. A review of the sequence listing of 08/850,713 demonstrates that SEQ ID Nos: 15 and 16 are not identical to the currently claimed SEQ ID Nos: 15 and 16. Further, a sequence search by STIC of the database of sequences which includes pending applications (including 08/850,713) failed to identify any alignment with that sequence while identifying perfect 100% matches with the current application itself and the immediate parent, 09/071,710 (to which priority is given). Therefore, for purposes of priority, this application received benefit until May 1, 1998.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 10-16, 33, 35, 38 and 39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In analysis of the claims for compliance with the written description requirement of 35 U.S.C. 112, first paragraph, the written description guidelines note regarding genus/species situations that "Satisfactory disclosure of a ``representative number'' depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.)

All of the current claims encompass a genus of nucleic acids which are different from those disclosed in the specification. The genus includes variants for which no written description is provided in the specification. This large genus is represented in the specification by only the particularly named SEQ ID Nos 15-16. Thus, applicant has express possession of only these 2 nucleic acids in a genus which comprises hundreds of millions of different possibilities. Here, no common element or attributes of the sequences are disclosed, not even the presence of certain domains. No structural limitations or requirements which provide guidance on the identification of sequences which meet these functional limitations is provided. Further, these claims encompass alternately spliced versions of the proteins, allelic variants including insertions and mutations, inactive precursor proteins which have a removable amino terminal end, and only specific amino acid sequences have been provided. No written description of alleles, of upstream or downstream regions containing additional sequence, or of alternative splice variants has been provided in the specification.

It is noted in the recently decided case The Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398 (Fed. Cir. 1997) decision by the CAFC that

> "A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is. See Fiers, 984 F.2d at 1169- 71, 25 USPQ2d at 1605- 06 (discussing Amgen). It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372- 73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material. "

In the current situation, the definition of the SEQ ID Nos 15-16 to comprise the sequence, to claim any 85% identical sequence or to any sequence which hybridizes to the sequence is precisely the situation of naming a type of material which is generally known to likely exist, but, except for the 16 specific sequences, is in the absence of knowledge of the material composition and fails to provide descriptive support for the generic claim.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that

> "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

The current situation is a definition of the compound solely but its functional utility, as a PS108 polynucleotide, without any definition of the particular changes due to the % identity, or selectively hybridizing language claimed.

In the instant application, certain specific SEQ ID NOs are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

> "...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception of any nucleic acids other than those expressly disclosed which comprise SEQ ID Nos 1-16. Therefore, the claims fail to meet the written description requirement by encompassing sequences which are not described in the specification.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. The rejection of claims 10-16 and 33 under 35 U.S.C. 102(b) as being anticipated by Gibco/BRL (1993/1994) p. 7-18 is withdrawn in view of the amendment.

6. Claims 11-16 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Genbank Accession No. W24907 (20 August 1996).

Genbank Accession No. W24907 teaches a 239 base pair sequence meeting the requirements of claims 11 and 33 which is 98% identical to SEQ ID NO: 15 and which has a 145 nucleotide fragment that is 100% identical as shown in the alignment below.

```
>gi|1302829|gb|W24907.1|  zb66h02.r1 Soares_fetal_lung_NbHL19W Homo
sapiens cDNA clone
           IMAGE:308595 5', mRNA sequence.
         Length = 239

 Score =  422 bits (213), Expect = e-114
 Identities = 222/226 (98%)
 Strand = Plus / Plus


Query: 1596 taacccaggaccttggaaattctactcatcccaaatgataattccaaatgctgttaccca 1655
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 14   taacccaggaccttggaaattctactcatcccaaatgataattccaaatgctgttaccca 73


Query: 1656 aggttagggtgttgaaggaaggtagagggtggggcttcaggtctcaacggcttccctaac 1715
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 74   aggttagggtgttgaaggaaggtagagggtggggcttcaggtctcaacggcttccctaac 133


Query: 1716 caccctcttctcttggcccagcctggttccccccacttccactcccctctactctctct 1775
          |||||||||||||||||||||||| ||||||||||||||||||||||||||||||||||
Sbjct: 134  caccctcttctcttggcccagcctngttccccccacttccactcccctctactctctct 193


Query: 1776 aggactgggctgatgaaggcactgcccaaaatttcccctaccccca 1821
          |||||||||||||||||||||||| | ||||||||||| |||||
Sbjct: 194  aggactgggctgatgaaggcactgccaanaatttcccctancccca 239
```

With regard to claims 12 and 13, the sequence is identical however produced.

With regard to claim 14, the sequence encodes an EST and inhernelty will encode an epitope.

With regard to claim 15, Genbank Accession No. W24907 teaches that the sequence is in the pT7T3D vector, which is operably linked to T7 or T3 control sequence, either of which can express the nucleic acid (see under features).

With regard to claim 16, Genbank Accession No. W24907 teaches that the nucleic acid is in the DH10B host cell (see under features).

Claim Rejections - 35 USC § 103

7. The rejection of claims 10-16, 33 and 35 under 35 U.S.C. 103(a) as being unpatentable over Guthrie et al (U.S. Patent 5,262,318) in view of Stratagene catalog (1988) p. 39 is withdrawn in view of the amendment.

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 10 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank Accession No. W24907 (20 August 1996) in view of Guthrie et al (U.S. Patent 5,262,318) in view of Stratagene catalog (1988) p. 39.

Genbank Accession No. W24907 teaches a 239 base pair sequence meeting the requirements of claims 11 and 33 which is 98% identical to SEQ ID NO: 15 and which has a 145 nucleotide fragment that is 100% identical as shown in the alignment below.

```
>gi|1302829|gb|W24907.1|  zb66h02.r1 Soares_fetal_lung_NbHL19W Homo
sapiens cDNA clone
           IMAGE:308595 5', mRNA sequence.
         Length = 239

 Score =  422 bits (213), Expect = e-114
 Identities = 222/226 (98%)
 Strand = Plus / Plus

Query: 1596 taacccaggaccttggaaattctactcatcccaaatgataattccaaatgctgttaccca 1655
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 14   taacccaggaccttggaaattctactcatcccaaatgataattccaaatgctgttaccca 73

Query: 1656 aggttagggtgttgaaggaaggtagagggtggggcttcaggtctcaacggcttccctaac 1715
          ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Sbjct: 74   aggttagggtgttgaaggaaggtagagggtggggcttcaggtctcaacggcttccctaac 133

Query: 1716 caccctctttctcttggcccagcctggttcccccacttccactcccctctactctctct 1775
          |||||||||||||||||||||||| ||||||||||||||||||||||||||||||||||
Sbjct: 134  caccctctttctcttggcccagcctngttcccccacttccactcccctctactctctct 193

Query: 1776 aggactgggctgatgaaggcactgcccaaaatttcccctaccccca 1821
          |||||||||||||||||||||||| | |||||||||| |||||
Sbjct: 194  aggactgggctgatgaaggcactgccaanaatttcccctanccccca 239
```

With regard to claims 12 and 13, the sequence is identical however produced.

With regard to claim 14, the sequence encodes an EST and inherently will encode an epitope, for example MIIPNAVTQG (from the first ATG).

With regard to claim 15, Genbank Accession No. W24907 teaches that the sequence is in the pT7T3D vector, which is operably linked to T7 or T3 control sequence, either of which can express the nucleic acid (see under features).

With regard to claim 16, Genbank Accession No. W24907 teaches that the nucleic acid is in the DH10B host cell (see under features).

Genbank Accession No. W24907 does not teach formation of a kit.

Guthrie teaches a cloning procedure in which DNA fragments are run onto DEAE paper and then ligated into a vector (see column 16, lines 18-67).

Stratagene catalog teaches a motivation to combine reagents into kit format (page 39).

It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to combine the method of Guthrie with the sequecne of Genbank Accession No. W24907 since Guthrie generically teaches cloning fragments using DEAE paper and a practitioner desiring to clone the EST of Genbank Accession No. W24907 would use the EST paper of Guthrie. Further it would have been *prima facie* obvious to combine these reagents into a kit format as discussed by Stratagene catalog since the Stratagene catalog teaches a motivation for combining reagents of use in an assay into a kit, "Each kit provides two services: 1) a variety of different reagents have been assembled and pre-mixed specifically for a defined set of experiments. Thus one need not purchase gram quantitites of 10 different reagents, each of which is needed in only microgram amounts, when beginning a series of experiments. When one considers all of the unused chemicals that typically accumulate in weighing rooms, desiccators, and freezers, one quickly realizes that it is actually far more expensive for a small number of users to prepare most buffer solutions from the basic reagents. Stratagene provides only the quantitites you will actually need,

premixed and tested. In actuality, the kit format saves money and resources for everyone by dramatically reducing waste. 2) The other service provided in a kit is quality control" (page 39, column 1).

Response to Arguments

11. Applicant's arguments filed January 6, 2005 have been fully considered but they are not persuasive.

Written Description

The issue is whether the claims comply with the written description requirement of 35 U.S.C. 112, first paragraph. In this analysis, Applicant does not focus on the legal framework, as enunciated in Lilly, which underlies the written description analysis for nucleic acids. While Applicant recognizes that a structure function relationship is required by the Federal Circuit in Lilly to support a generic claim under the written description requirement, applicant has not amended the claim to include any functional element such as that found in Example 9 of the Written description guidelines. Applicant should also note that a "representative number of species" is required. This is considered by the USPTO written description guidelines which note that in an unpredictable art, a single species is not sufficient to describe the genus.

It is the absence of any structure function relationship and the absence of a representative number of species which supports the conclusion that there is insufficient descriptive support for the current claims. This argument rests on three grounds. First, each of the single sequences, of the 2 different sequences that are now claimed, are not representative of the genus of any sequence which is 85% identical to those

sequences. Second, the claims entirely lack a structure function relationship since no function whatsoever is given for the nucleic acid sequences in the claims.

Absence of a representative number of species

In the current case, the first question is what constitutes a generic claim. The genus of polypeptides represents every possible variation which could occur in SEQ ID Nos: 15-16, that has 85% identity. Using the 2143 nucleotides of SEQ ID NO: 15 as an example, this would permit variation in 15% or 321 of the nucleotides. So the genus of variants would be greater than 4^{321}. (It would be greater because this analysis ignores the order of the nucleotides, which is significant, and therefore would yield a larger number). In order to provide a representative number of species, in a genus which contains literally 4^{321} (or written out fully, approximately
182,497,624,704,887,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,
000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,
000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,
000,000,000,000,000) different members, the court in Lilly required "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. (Lilly at page 1406)." (As a side comment, the genus size here is larger than that at issue in Deuel). Lilly continues to note that in other cases, two chemical compounds in a subgenus were insufficient to describe that genus. In the current case, Appellant argues that the single species of a single SEQ ID

NO is sufficient to describe 4^{321} other sequences for which no description whatsoever is given. These sequences may be of any size or structure, so long as they are 85% identical. Applicant's analysis is flawed since there is no expectation in the instant case of insubstantial variation because no functional limitation is provided in the claim. The only function to which Applicant points is hybridization, but this provides literally no limitation on the nucleic acid because hybridization is not a function that is catalytic. In any case, the guidelines intended that the structure function relationship involve a function which imposes structural delimitations. In the example, enzyme activity delimits the structure because certain domains must be conserved or the enzymatic catalytic activity will not operate. Further, the percent homology was significantly higher, at 95%. The function of hybridization provides absolutely no guidance or information regarding the structure and does not delimit the structure in even the smallest or most miniscule possible way.

Applicant appears to also be making the argument that the size of the genus is not relevant. This is not found persuasive because the size of the genus is a central issue. If the genus were small, a written description rejection would be less likely, since the examples would be more representative of the genus. Here, where the genus includes
182,497,624,704,887,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,
000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,
000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,000,
000,000,000,000,000 different members, literally trillions and trillions of possible

molecules, none of which are disclosed or taught by Applicant, the argument that the demonstrated species is representative is not found persuasive.

Absence of any structure-function relationship

Second, when Applicant relies upon the analysis of the written description guidelines, this analysis is based upon the assumption that there will be insubstantial variation, as noted in many of the examples including example 9. However, Applicant's analysis is flawed since there is no expectation in the instant case of insubstantial variation because the functional limitation devolves solely to the ability of the nucleic acid to hybridize. This is not like example 9; where the functional limitation involved a protein which retained adenylate cyclase activity. In the example 9 case, the argument of insubstantial variation was that there was an expectation that stringently hybridizing proteins which retained the specific function of stimulating adenylate cyclase would differ insubstantially. Applicant's fundamental position fails to equate with the written description guidelines because in the guidelines, there is function correlated to the structure. Applicant's claims, however, lack any function whatsoever. So consonant with the case law in Lilly, Enzo and the other written description decision of the Federal Circuit, it is clear that the current claims fail to meet the written description requirement because there is literally no structure whatsoever.

Applicant's conclusion that no more than a single sequence and specific high stringency conditions are required to support a genus claim based upon the guidelines is consequently incorrect. The guidelines require more. They require a structure function relationship.

The claim scope broadly encompasses sequences from other species

Finally, when Applicant argues that the case is different from the issues cited in Lilly and Fiers, Applicant fails to appreciate the breadth of the claim. The current claim clearly reads on sequences found not only in humans, but in other species. This was the crux of the decision in Lilly, that a rat insulin sequence did not provide sufficient breadth to provide descriptive support for a claim which encompassed human insulin nucleic acid sequences. Applicant's claim suffers from the same flaw, since the claim would clearly encompass sequences from other species. For example, an alignment of SEQ ID NO: 5 with the mouse Genbank Accession No. BC031381 shows an 92% alignment. (This is post filing date art). So the claim as written would encompass a mouse sequence, not described by Applicant, which is the express problem raised in Lilly. It is clear that Applicant did not have possession of this sequence, since there was no recognition of the particular changes that would result in the sequence.

```
gi|21594808|gb|BC031381.1| Mus musculus prostate cancer associated protein 6,
mRNA (cDNA clone
           MGC:32471 IMAGE:5050610), complete cds
         Length = 3354

 Score =  240 bits (121), Expect = 1e-60
 Identities = 167/181 (92%), Gaps = 1/181 (0%)
 Strand = Plus / Plus


Query: 1    tggatagtgccttcctgctgtcccaggtggccccatccctgtttatgggctccattgtcc 60
            |||| |||||||| |||||||||||||||| || |||||||| ||||||||||||||||
Sbjct: 1926 tggacagtgcctttctgctgtcccaggtggctccgtccctgttcatgggctccattgtcc 1985


Query: 61   agctcagccagtctgtcactgcctatatggtgtctgccgcaggc-tgggtctggtcgcca 119
            |||| ||||| |||||||||||||||||| || || |||||| ||||||||||||||||
Sbjct: 1986 agctgagccactctgtcactgcctatatggtatcagctgcaggcttgggtctggtcgcca 2045


Query: 120  tttactttgctacacaggtagtatttgacaagagcgacttggccaaatactcagcgtaga 179
            |||||||||||||||||||||| ||||||||| |||||||||||||||||| |||||
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Sbjct: 2046 tttactttgctacacaggtagtgtttgacaagaacgacttggccaaatactcagtgtaga 2105

Query: 180  a 180
             |
Sbjct: 2106 a 2106
```

Therefore the claims clearly encompass sequences which were neither taught nor described by the current specification. The claims include a single species which is not representative of the full scope of the genus. The guidelines support the rejection, particularly the requirement of Example 9 for a structure function relationship. Therefore, the written description rejection is maintained.

Prior art

Applicants amendment to 15 nucleotides and 85% identity overcomes the prior art. However, since new prior art is applied that is necessitated by this amendment, Applicants claim analysis will be addressed. Applicant interprets the claim as requiring 85% identity over the full length of any sequence rather than 85% over the length of the matching fragment. This interpretation is not correct since the claim uses the open "having" langauge with regard to the fragments. The claim states that the polynucleotide has 85% identity with fragments of at least 15 nucleotides. So the comparison is not over the entire length, as argued by Applicant, since the polynucleotide is open to the inclusion of additional sequence. Therefore, the analysis is simply over the matching regions, not the full length.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Fredman whose telephone number is (571)272-0742. The examiner can normally be reached on 6:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571)272-0782. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey Fredman
Primary Examiner
Art Unit 1637
2/9/04